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WASHINGTON, DC 20007

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,905

Applicant(s)

TANG ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
4a) Of the above claim(s) 1,2,8-10,13-43,45-84 and 86 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 3-7,11,12,44,85 and 87-95 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/19/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

- [1]** Claims 1-95 are pending in the application.
- [2]** Applicants' amendment to the claims, filed November 19, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicant's amendment to the specification, filed November 19, 2004, is acknowledged.
- [4]** Receipt of an information disclosure statement (IDS), filed November 19, 2004, is acknowledged.
- [5]** Applicants' arguments filed November 19, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Lack of Unity

- [7]** Applicants traverse the lack of unity requirement for the reasons of record. For the reasons of record as set forth at item [4] of the Office action mailed August 19, 2004, the inventions of Groups I-CCXXXIV do not have unity of invention.
- [8]** The requirement was made FINAL in a previous Office action.

[9] Claims 1-2, 8-10, 13-43, 45-84, and 86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[10] Claims 3-7, 11-12, 44, 85, and 87-95 are being examined on the merits.

[11] In order to clarify the record, it is noted that applicants assert claims 1-2, 8-10, 13-43, 45-84, and 86 are being examined on the merits (p. 21, bottom of the response filed November 19, 2004). However, this is inaccurate as claims 1-2, 8-10, 13-43, 45-84, and 86 are withdrawn from consideration and claims 3-7, 11-12, 44, 85, and 87-95 are being examined on the merits.

Priority

[12] Applicant's claim for domestic priority under 35 USC § 119(e) to US provisional application 60/144,992, filed July 22, 1999, and US provisional application 60/168,858, filed December 2, 1999, is acknowledged. The sequences of SEQ ID NO:2 and 17 of the instant application are disclosed in provisional application number 60/144,992 as SEQ ID NO:2 and 5, respectively. The sequences of SEQ ID NO:2 and 17 of the instant application do not appear to be disclosed in application 60/168,858.

Specification/Informalities

[13] The objection to the title of the invention as not being descriptive is maintained for the reasons of record as set forth at item [11] of the Office mailed August 19, 2004. While applicants suggest a title that is allegedly "brief but technically accurate and

descriptive," the title of the invention has not been amended. It is suggested that applicants amend the title in accordance with their suggested title.

Claim Objections

[14] Claims 87 and 92-93 are objected to in the recitation of "nucleotide molecules." In view of the context of the claims, it is clear that the term is meant to refer to a nucleic acid molecule and not a nucleotide molecule. It is suggested that applicants amend the term "nucleotide molecule" to "nucleic acid molecules."

Claim Rejections - 35 USC § 101

[15] The utility rejection of claims 3-7, 11-12, 44, 85, and 87-95 under 35 U.S.C. 101 and the corresponding enablement rejection of claims 3-7, 11-12, 44, 85, and 87-95 under 35 U.S.C. 112, first paragraph are maintained for the reasons of record as set forth at items [15] and [16] of the Office action mailed August 19, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue that, on the basis of the MPEP, the original specification, and the attached references of Yamashita et al., Oikawa et al., and Gassler et al. (all cited in the IDS filed November 19, 2004), the claimed invention has a specific and substantial asserted utility. Applicants argue the specification asserts the claimed nucleic acid is useful in the diagnosis, treatment, and prevention of immune, neuronal, and reproductive disorders and cell proliferative disorders including cancer, the claimed nucleic acid is expressed in gastrointestinal, reproductive, and

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hematopoietic tissue, is associated with cancer, inflammation, and cell proliferative diseases, disorders, and conditions, and the specification discloses "extensive teachings" as to how the claimed invention provides therapeutics and diagnostics.

Applicants' argument is not found persuasive.

It is noted that applicants' arguments appear to indicate that the teachings of Yamashita et al., Oikawa et al., and Gassler et al. are required for a "real-world" use of the claimed nucleic acid ("on the basis of...the attached publication...the present application possesses specific and substantial utility" (p. 23, bottom of the instant response). However, it is noted that the cited references of Yamashita et al. and Gassler et al. were published *after* the time of the invention. MPEP 2164.05(a) makes clear that the specification must be enabling as of the filing date of the application and, while MPEP 2164.05(a) states, "[t]he specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public," it is noted that the teachings of Yamashita et al. and Gassler et al. were not available to the public at the time of the invention and were not well-known to those of skill in the art. Even if applicants argue the teachings of Yamashita et al. and Gassler et al. are not required for patentable utility, it is noted that the specification fails to provide the necessary *specific* guidance for using the claimed nucleic acid in the diagnosis and/or treatment of any disease and the teachings of Oikawa et al. fail to compensate for the lack of guidance in the specification. As stated in a previous Office action, the specification fails to disclose any specific cell proliferative, immune, neuronal, and/or reproductive disorder(s) that can be diagnosed,

treated, or prevented using the claimed polynucleotide. In the absence of such disclosure, one of skill in the art is left to determine which – if any - cell proliferative, immune, neuronal and/or reproductive disorder(s) can be diagnosed, treated, or prevented using the claimed polynucleotide and the specific conditions necessary for such. The specification merely provides generic teachings that are meant to apply to any of the 13 originally claimed nucleic acids of SEQ ID NO:16-17 and 19-29. There is no specific guidance for using the claimed nucleic acid for treatment or diagnosis and, as such, further experimentation is required to practice this utility. Applicants are invited to point out how a skilled artisan, using the claimed invention and the instant specification for guidance, can diagnose or treat a disease. This type of utility is not substantial as the specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). As stated in Brenner v. Manson, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), “[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Thus, the claimed invention is not supported by a specific and substantial asserted utility and the examiner knows of no well-established use for the claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph

[16] Claims 3, 6-7, 11-12, 85, and 87-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 3 (claims 6-7 and 94 dependent therefrom) and 11 (claims 12, 85, 87-93, and 95 dependent therefrom) are indefinite in the recitation of "synthetase activity." This rejection is necessitated by amendment. A skilled artisan recognizes that there are numerous distinct enzymatic activities that can be classified as "synthetase" activities as evidenced by applicants' own disclosure, which describes, *e.g.*, tRNA synthetase (p. 1), acyl-CoA or acetyl-CoA synthetase (p. 2), and glutamine synthetase (p. 3) enzymatic activities. As such, it is unclear as to the scope of claimed polynucleotides that are encompassed by the claims. It is suggested that applicants clarify the intended "synthetase" activity.

[b] The rejection of claim 87 (claims 88-93 dependent therefrom) as being indefinite in the recitation of "specifically hybridizable" is maintained for the reasons of record as set forth at item [17], part [c] of the Office action mailed August 19, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification clearly defines hybridization conditions in the specification such that a skilled artisan would understand the metes and bounds of the term. Applicants' argument is not found persuasive.

The specification fails to define those conditions under which specific hybridization is to occur. MPEP 2111 directs the examiner to give claims their broadest reasonable interpretation in light of the specification. The MPEP also directs the

examiner not to read limitations from the specification into the claims. As no specific definition has been provided for the term "specifically hybridizable" or the conditions under which such hybridization is to occur, the term remains indefinite and it is unclear as to the scope of recited polynucleotides.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[17] Claims 3-7, 11-12, 44, 85, and 87-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection and is necessitated by amendment.

Claim 3 (claims 4-6 and 94 dependent therefrom) recites the limitation of a nucleic acid encoding "an amino acid sequence having at least 90% sequence identity to SEQ ID NO:2 and having synthetase activity." Claim 11 (claims 12, 44, 85, 87-93, and 95 dependent therefrom) recites the limitation of "a polynucleotide sequence having at least 90% sequence identity to SEQ ID NO:17 and encoding a polypeptide having synthetase activity." MPEP 2163 directs applicants to show support for amendments to

the claims. Applicants cited support for these limitations is at page 4, lines 30-33 of the specification. However, the examiner can find no support for these limitations at page 4, lines 30-33 of the specification. It is suggested that applicants point out support in the specification, claims, or drawings as originally filed for these limitations.

[18] The written description rejection of claims 3, 6-7, 11-12, 85, and 87-95 is maintained for the reasons of record as set forth at item [18] of the Office action mailed August 19, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification "contains extensive functional and structural descriptions of the specifically recited sequences" and claim 3 part (b) has been amended to recite both structural and functional features. Applicants' argument is not found persuasive.

As stated in a previous Office action (and undisputed by applicants) the species encompassed by the genus of claimed or recited polynucleotides are widely variant and the single representative disclosed species of SEQ ID NO:17 fails to represent all members of the claimed genus. Regarding claims 3 and 11, it is noted that, while parts b) and c) of claim 3 and part b) of claim 11 are limited to a genus of nucleic acids encoding polypeptides "having synthetase activity," it is noted that even this genus is widely variant with respect to the numerous "synthetase" activities that are encompassed by the term as evidenced by applicants' disclosure as described above. Moreover, claim 3 recites "[a]n isolated polynucleotide encoding a polypeptide *comprising...*" As such, part d) encompasses any nucleic acid encoding a polypeptide comprising any immunogenic fragment of SEQ ID NO:2 with any function. Similarly,

claim 12 encompasses nucleic acids with any 60 contiguous nucleotide fragment of the nucleic acid of claim 11 having any function. Claims 87-89 and 91-93 are drawn to an array comprising nucleic acids having essentially any structure (particularly in view of the indefiniteness of the term "specifically hybridizable") and any function. Claims 94 and 95, while being limited structurally, can have any function. Thus, the genus of claimed or recited nucleic acids encompass species that are widely variant and in this case, the single representative species of SEQ ID NO:17 fails to represent all species of claimed or recited nucleic acids.

[19] Even if applicant demonstrates a specific and substantial or well-established utility for a nucleic acid encoding SEQ ID NO:2, the following rejection still applies. The scope of enablement rejection of claims 3, 6-7, 11-12, 85, and 87-95 is maintained for the reasons of record as set forth at item [19] of the Office action mailed August 19, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: It is noted that applicants incorrectly refer to a rejection of "[c]laims 1-6, 8, 10-11, and 15." This appears to be a "copy-paste" error and the examiner will interpret the response as being directed to the rejection of claims 3, 6-7, 11-12, 85, and 87-95. Regarding the scope of the claims, applicants argue the breadth of the claims is limited to specifically defined sequences and sequences with specifically defined characteristics. Applicants' argument is not found persuasive.

The nucleic acid of parts b) and c) of claim 3 and part b) of claim 11 is so broad as to encompass nucleic acids encoding polypeptides having any synthetase activity and numerous "synthetase" activities that are encompassed by the term as evidenced

by applicants' disclosure as described above. Moreover, claim 3 has been amended to recite "[a]n isolated polynucleotide encoding a polypeptide *comprising...*" As such, part d) encompasses any nucleic acid encoding a polypeptide comprising any immunogenic fragment of SEQ ID NO:2 with any function. Similarly, claim 12 encompasses nucleic acids with any 60 contiguous nucleotide fragment of the nucleic acid of claim 11 having any function. Claims 87-89 and 91-93 are drawn to an array comprising nucleic acids having essentially any structure (particularly in view of the indefiniteness of the term "specifically hybridizable") and any function. Claims 94 and 95, while being limited to the recited structure, can have any function. In this case, the broad scope of the claims is not commensurate with the enablement provided by the disclosure. The examiner maintains the position that the specification is enabling only for a nucleic acid encoding SEQ ID NO:2.

Regarding the state of the art and level of skill in the art, applicants argue the state of the art and level of skill in the art is high and the methods for making nucleic acid variants is routine. Applicants' argument is not found persuasive.

While it is acknowledged that methods of altering a protein-encoding sequence were known at the time of the invention, one of skill in the art recognizes that there is a high level of unpredictability in altering the sequence of a protein-encoding nucleic acid as there is no way of predicting the effects *a priori* of altering a protein-encoding nucleic acid with an expectation of obtaining a polypeptide having the desired activity and/or utility.

Regarding the predictability in the art, applicants argue the predictability is moderate to high as the specification provides "extensive guidance" including examples of "signature motifs" and further argue that methods of obtaining nucleic acid variants is routine. Applicants' argument is not found persuasive.

It is noted that applicants fail to elaborate on the "extensive guidance" that is provided for altering the nucleic acid of SEQ ID NO:17 with an expectation of obtaining a nucleic acid having the desired activity and/or utility. While the specification implies (but does not expressly state) SEQ ID NO:2 has an AMP binding domain and a long-chain acyl-CoA synthetase domain, there is no further guidance for altering the nucleic acid of SEQ ID NO:17. As stated in a previous Office action, the teachings of Branden et al. as exemplified by Witkowski et al., which are undisputed by applicants, represent the state of the art and the high level of unpredictability in altering the sequence of a protein-encoding nucleic acid.

Regarding working examples, applicants argue the specification discloses working examples and Table 2 provides structural and functional features such that a skilled artisan could make the broad scope of claimed or recited nucleic acids with an expectation of success without undue experimentation. Applicants' argument is not found persuasive.

The working examples are merely general teachings that apply to all of the disclosed nucleic acids and are not specific to SEQ ID NO:17. A skilled artisan would recognize that such general teachings fail to provide the guidance necessary for altering a protein-encoding nucleic acid with an expectation of obtaining a nucleic acid having

the desired activity and/or utility. Thus, at least for the reasons of record (particularly those presented in the detailed analysis of the Factors of *In re Wands* at pp. 13-16 of the Office action mailed August 19, 2004) and the reasons stated herein, undue experimentation is required to make and use the broad scope of claimed or recited nucleic acids.

Double Patenting

[20] The obviousness-type double patenting rejection of claims 3, 6-7, 11-12, 85, and 87-90 as being unpatentable over claims 1, 4, 7-9, and 23-24 of copending US Application 10/098,841 is withdrawn in view of abandonment of application 10/098,841. However, if application 10/098,841 is revived from abandonment, the instant rejection may be re-instated.

[21] The obviousness-type double patenting rejection of claims 85 and 87-90 as being unpatentable over claim 3 of copending US Application 09/974,298 (the "298 application") is maintained for the reasons of record as set forth at item [21] of the Office action mailed August 19, 2004, particularly in view of applicants' failure to address the instant rejection, indicating that applicants concede to the examiner's stated position.

Claim Rejections - 35 USC § 102

[22] The rejection of claims 3, 6-7, 11-12, and 94-95 under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US Patent Application Publication 2003/0073129 A1) is maintained for the reasons of record as set forth at item [22] of the Office action mailed

August 19, 2004, particularly in view of applicants' failure to address the instant rejection, indicating that applicants concede to the examiner's stated position.

Conclusion

[23] Status of the claims:

- Claims 1-95 are pending.
- Claims 1-2, 8-10, 13-43, 45-84, and 86 are withdrawn from consideration.
- Claims 3-7, 11-12, 44, 85, and 87-95 are rejected.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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David J. Steadman, Ph.D.

Primary Examiner

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